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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,661	11/24/2003	Anton Berns	8535-068-999	7750

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,661	BERNS ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 1006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-127* is/are pending in the application.

4a) Of the above claim(s) *99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-98 and 100-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a CON of 09/253,818, filed 02/19/1999, now US PAT 6,653,113, which is a CON of 09/116,298, filed 07/15/1998, now ABN, which is a CON of 08/908,348, filed 08/07/1997, now US PAT 5,789,215, which is a CON of 08/700,324, filed 08/08/1996, now ABN, which is a CON of 08/563,138, filed11/27/1995, now ABN, which is a CON of 08/216,121, filed 03/22/1994, now ABN, which is a CON of 07/748,342, filed 08/20/1991, now ABN.

Applicants' amendment filed June 6, 2006 has been received and entered. Claims 1-88 have been cancelled. Claims 89-127 have been added. Claims 89-127 are pending.

Election/Restrictions

Applicant's election of Group I and the species of mouse embryonic stem cell in the reply filed on June 6, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly added claims 89-127 are generally drawn to the elected invention. Claim 99 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species-reciting cell types other than embryonic stem cells, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 6, 2006. Claims 89-98, 100-127 are currently under examination as drawn to a modified mouse embryonic stem cell.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statements (IDS) are in compliance with the provisions of 37 CFR 1.97. It is noted that several of the foreign patent documents are not in English, and only have been considered with respect to the English abstract translation provided (pages 2-3 of IDS submitted October 24, 2003- references are present in application number 09/253,818). The information disclosure statement is being considered by the examiner.

It is noted that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, multiple references are cited throughout the specification, however a complete one to one comparison of the IDS and these listings has not been done. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 89-98, 100-127 are objected to because of the following informalities:

The original claims restricted to group I recited "a modified animal cell or a progeny", while the new claims are drawn to "a composition". Technically, a composition can encompass an animal, which is encompassed by non-elected group II. Amending the claims to an isolated cell or modified cell to more clearly reflect the elected group is required.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 89-98, 100-127 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,653,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims.

Claims 89-98, 100-127 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,789,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims.

In each case the independent claims are drawn to a method for modifying the genome of a target cell, and dependent claims set forth that the animal is a mouse and provide for constructs that for various types of alterations of the genome. The present claims are drawn to a product by process wherein the product is made by the method set forth in '113 and 215.
The dependent claims set forth limitations of the method steps rather than any structural property of the resulting cell provide by practicing said method. Effectively, the methods of each result in the products instantly claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 89-98, 100-127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are vague and confusing as they are drawn to the product by process. More specifically, independent claim 89 recites a composition comprising a modified cell or a progeny-however claim 90 clearly indicates that the genome does not have to be altered. The metes and bounds of the claims are indefinite because the product claimed is relative to how or in what way the process is practiced. Moreover, dependent

claims set forth specific % amounts of recombination or specific events of gene conversion/alteration which can at best be relative to the materials used and not specifically controlled by any other means. The metes and bounds of the claim can not be determined clearly because the are relative to how one practices the method or the materials used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 89-98, 100-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Capecchi *et al.* (IDS reference C06-1989).

The claims are drawn to a product by process and recite "progeny". As evidenced by claim 90, integration of a modifying sequence is not even a requirement of claim 89, therefore a progeny does not have to contain a modification to the genome. Other dependent claims set forth various features of the modifying sequence or how the method is generally practiced, yet again there is no requirement that the progeny contain the modification. A reasonable interpretation of the claim drawn to a progeny encompasses a mouse embryonic stem cell with no modification made to the genome. When a modification is required as in claim 90, the claims set forth a variety of resulting genetic events, or provisions for the % of cells that have

undergone homologous recombination, but sets no limitation on the progeny. Dependent claims only requiring selecting by any means (claim 113), or that the modification is a combination of possible events related to the nature of the construct used to effect homologous recombination again provide no requirement that the progeny have any alteration. Even when certain amount of identity is recited or the alteration of the gene is recited, there is no clear nor specific structural requirement in the final cell. For example the starting material is an mouse embryonic stem cell that comprises a deletion of gene encompassing a promoter through the first intron and exon sequences. A construct is made and used to insert the promoter and the first intron and exon into the mouse embryonic cell, effectively providing a mouse embryonic stem cell with no alterations. The claims are very broad where they encompass any starting material, the use of any construct, and thus any effective change the artisan could imagine.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Capecchi *et al.* teach method for producing an alteration in a gene of interest by targeting through homologous recombination. Capecchi *et al.* use mouse embryonic stem cells

Claims 89-98, 100-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Capecchi *et al.* (US Patent 5,464,764).

The breadth of the claims are summarized above.

Capecchi *et al.* teach method for producing an alteration in a gene of interest by targeting through homologous recombination. Capecchi *et al.* use mouse embryonic stem cells

Conclusion

No claim is allowed.

The claims are drawn to a product by process, and in the broadest structural limitations recited in the claims, the product can be any cell comprising any insertion, deletion, substitution, or combination thereof (see dependent claim 114 for example). As a product by process, effectively any cell that had an insertion, a deletion, a substitution, or a combination thereof would anticipate these claims as meeting the structural limitations required by the claims. Furthermore, any "normal" cell could anticipate the breath of the claims since the starting material and the final resulting cell is not specifically defined. While there may be certain aspects of the methodology that are novel to the art of record, the method fails to provide any unique structural property of the resulting cell that could be distinguished by a cell made by another method or that normally exists in nature (such as an isolated cell from a subject with cystic fibrosis). As acknowledged in the summary of the invention, the present invention provides for novel methods (page 3), however the method does not provide a unique product only at best increased efficiency (page 5).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AU 1632